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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,639	11/15/2005	Daniel Yachia	26753U	1745
20529	7590	05/04/2007		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER SCHELL, LAURA C	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 05/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No. 10/533,639	Applicant(s) YACHIA ET AL.	
	Examiner Laura C. Schell	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/31/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Santini, Jr. et al. (US Patent No. 6,491,666). Santini discloses a medical device for controlled release of one or more substances into a body cavity containing an electrolytic fluid (col. 15, lines 39-41) comprising: a power supply having first and second terminals (col. 14, lines 5-7); a plurality of blister-like vesicles mounted on a first surface (Fig. 2a-2d, the blister-like vesicles are 230, 330, 430, 530a, 530b), each vesicle having at least a metallic portion formed from a first metal (col. 4, lines 20-22 and col. 8, lines 61-67); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed (col. 14, lines 8-45); and a cathode formed from a second metal attached to the second terminal of the power supply (col. 4, lines 53-59 and col. 6, line 62 through col. 7, line 15); wherein the cathode is separate from the anodes by a space

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that is accessible by the electrolytic fluid when the device is in the body cavity (Figs. 2a-2d).

In reference to claim 2, Santini discloses a processor configured to close one or more switches at one or more predetermined times (col. 14, lines 5-45).

In reference to claim 3, Santini discloses one or more magnetic particles (col. 4, lines 20-22 and col. 8, lines 61-67).

In reference to claim 4, Santini discloses that the switches are closed by means of a remote control (col. 15, lines 20-22).

In reference to claim 5, Santini discloses that the body cavity is a urinary bladder or a digestive tract organ (col. 15, lines 39-41).

In reference to claim 6, Santini discloses that the anodes are formed from copper and the cathode is formed from zinc (col. 4, lines 20-22 and col. 8, lines 61-67).

In reference to claim 12, Santini discloses that the one or more substances is an antibiotic (col. 9, line 54).

In reference to claim 13, Santini discloses that the one or more substance are radioactive substances (col. 9, line 54).

In reference to claim 14, Santini discloses one or more monitoring device for parameters in the body cavity (col. 17, line 58 through col. 18, line 40).

In reference to claim 15, Santini discloses that the one or more of the monitoring devices monitors a parameter of the body cavity such as composition of the electrolytic fluid (col. 17, line 58 through col. 18, line 40).

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In reference to claim 16, Santini discloses (col. 2, lines 28-31 and col. 14, lines 8-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini, Jr. et al. (US Patent No. 6,491,666) in view of Yachia et al. (US Patent No. 6,293,923). Santini discloses the device substantially as claimed except for the inflatable balloon with magnetic portion and valve. Yachia, however, discloses an inflatable balloon (Fig. 5b, balloon is 1) with magnetic portion (Fig. 13, 3) and a self-sealing valve (Figs. 2, 3a and 3b where valve is 5). Yachia further discloses that the device after inflation of the balloon either floats or sinks in the electrolytic fluid (col. 5,

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lines 64-65). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Santini with the balloon and its magnetic and valve elements, as taught by Yachia, in order to provide a device which can be delivered to the treatment area and positioned properly to allow for the most effective treatment possible (abstract).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini, Jr. et al. (US Patent No. 6,491,666) in view of Yachia et al. (US Patent No. 6,293,923). Santini discloses a system for treating a body cavity of an individual, the system comprising a device comprising: a power supply having first and second terminals (col. 14, lines 5-7); a plurality of blister-like vesicles mounted on a first surface (Fig. 2a-2d, the blister-like vesicles are 230, 330, 430, 530a, 530b), each vesicle having at least a metallic portion formed from a first metal (col. 4, lines 20-22 and col. 8, lines 61-67); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed (col. 14, lines 8-45); and a cathode formed from a second metal attached to the second terminal of the power supply (col. 4, lines 53-59 and col. 6, line 62 through col. 7, line 15); wherein the cathode is separate from the anodes by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Figs. 2a-2d). Santini, however, does not disclose an applicator for inserting and removing the device from the body. Yachia, however, discloses an applicator for inserting and removing the device from the body

(Figs. 5a, 5b, 9-11). Yachia further discloses that the applicator is fitted at an end thereof with a gripping device for releasably gripping the device (Fig. 5b, 23). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Santini by using the applicator to deliver and retrieve the treatment device, as taught by Yachia, in order to precisely place the device in the desired location with the body cavity, such as the bladder, as taught by Yachia (abstract).

Claims 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini, Jr. et al. (US Patent No. 6,491,666) in view of Yachia et al. (US Patent No. 6,293,923). Santini discloses the device substantially as claimed including a system for treating a body cavity of an individual, the system comprising a device comprising: a power supply having first and second terminals (col. 14, lines 5-7); a plurality of blister-like vesicles mounted on a first surface (Fig. 2a-2d, the blister-like vesicles are 230, 330, 430, 530a, 530b), each vesicle having at least a metallic portion formed from a first metal (col. 4, lines 20-22 and col. 8, lines 61-67); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed (col. 14, lines 8-45); and a cathode formed from a second metal attached to the second terminal of the power supply (col. 4, lines 53-59 and col. 6, line 62 through col. 7, line 15); wherein the cathode is separate from the anodes by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Figs. 2a-2d). Santini, however, does not disclose that the device includes

an inflatable balloon or applicator for inserting and removing the device. Yachia, however, discloses an inflatable balloon (Fig. 5b, balloon is 1) and an applicator for inserting and removing the device from the body (Figs. 5a, 5b, 9-11). Yachia further discloses that the applicator is fitted at an end thereof with a gripping device for releasably gripping the device (Fig. 5b, 23). Yachia also discloses an inflating device for inflating the balloon (Fig. 4a, 7). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Santini by using the balloon and applicator to deliver and retrieve the treatment device, as taught by Yachia, in order to precisely place the device in the desired location with the body cavity, such as the bladder, as taught by Yachia (abstract).

In reference to claim 19, Santini discloses the device substantially as claimed except for a magnetic displacing member. Yachia, however, discloses a magnetic displacing member (Fig. 13, 51 and 52) for displacing the device within the body cavity. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Santini with the magnetic displacing member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 4, lines 62-65).

In reference to claims 20 and 21, Santini discloses the device substantially as claimed except for an immobilizing member. Yachia, however, discloses an immobilizing member (Fig. 14, 75) comprising a magnetic portion (72), said immobilizing member being secured onto the individual's body for immobilizing the device at a desired location in the body cavity (Fig. 14). Yachia further discloses that the

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immobilizing member is a hygienic pad configured to be placed in a garment of the individual (col. 7, lines 39-41). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Santini with the magnetic immobilizing member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 5, lines 2-3).

In reference to claims 22-24, Santini discloses the device substantially as claimed except for the gripping device having flanges, being magnetic and the inflating device comprising an injector. Yachia, however, discloses that the gripping device has flanges (Fig. 5a, 23), is magnetic (Fig. 11, 29) and the inflating device comprises an injector (Figs. 4a and 4b, 7). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Santini with the magnetic gripping member and inflating member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 6, lines 56-61).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini, Jr. et al. (US Patent No. 6,491,666) in view of Yachia et al. (US Patent No. 6,293,923). Santini discloses a method for releasing one or more substances into a body cavity containing an electrolytic fluid of an individual (col. 15, lines 39-41) comprising: a power supply having first and second terminals (col. 14, lines 5-7); a plurality of blister-like vesicles mounted on a first surface (Fig. 2a-2d, the blister-like vesicles are 230, 330,

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430, 530a, 530b), each vesicle having at least a metallic portion formed from a first metal (col. 4, lines 20-22 and col. 8, lines 61-67); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed (col. 14, lines 8-45); and a cathode formed from a second metal attached to the second terminal of the power supply (col. 4, lines 53-59 and col. 6, line 62 through col. 7, line 15); wherein the cathode is separate from the anodes by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Figs. 2a-2d); loading the one or more substances into the vesicles of the device (col. 4, line 27); inserting the device into the body cavity (col. 15, lines 39-41). Santini, however, does not disclose the steps of expanding the balloon or displacing the balloon. Yachia, however, discloses expanding a balloon in a urinary bladder (Fig. 9) and displacing the balloon within the bladder to a desired location (Fig. 13). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Santini with inflating the balloon and moving it within the bladder, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 4, lines 62-65).

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini, Jr. et al. (US Patent No. 6,491,666) in view of Yachia et al. (US Patent No. 6,293,923). Santini discloses a method for releasing one or more substances into a

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body cavity containing an electrolytic fluid of an individual ((col. 15, lines 39-41) comprising: a power supply having first and second terminals (col. 14, lines 5-7); a plurality of blister-like vesicles mounted on a first surface (Fig. 2a-2d, the blister-like vesicles are 230, 330, 430, 530a, 530b), each vesicle having at least a metallic portion formed from a first metal (col. 4, lines 20-22 and col. 8, lines 61-67); for each vesicle, an electrical connection between the metallic portion of the vesicle and the first terminal of the power supply, each connection including a switch so as to allow the metallic portion to function as an anode when the switch is closed (col. 14, lines 8-45); and a cathode formed from a second metal attached to the second terminal of the power supply (col. 4, lines 53-59 and col. 6, line 62 through col. 7, line 15); wherein the cathode is separate from the anodes by a space that is accessible by the electrolytic fluid when the device is in the body cavity (Figs. 2a-2d); inserting the device into the body cavity (col. 15, lines 39-41). Santini, however, does not disclose an inflatable balloon or expanding the balloon in the body cavity. Yachia, however, discloses an inflatable balloon (Fig. 4a and 4b, 1) and inflating the balloon in the body cavity (Fig. 4b). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Santini by using the balloon, as taught by Yachia, in order to precisely place the device in the desired location with the body cavity, such as the bladder, as taught by Yachia (abstract).

In reference to claim 27, In reference to claim 19, Santini discloses the device substantially as claimed except for displacing the device within the body cavity to a desired location. Yachia, however, discloses a magnetic displacing member (Fig. 13,

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51 and 52) for displacing the device within the body cavity. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Santini with the magnetic displacing member, as taught by Yachia, in order to allow the physician to position the implanted device correctly to bring about the most effective treatment at the delivery site (col. 4, lines 62-65).

In reference to claim 28, Santini discloses that the one or more substances is an antibiotic (col. 9, line 54).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in cursive script, reading "Kevin C. Sirmons".